PARENT INFORMATION SHEET: COV002

Investigating a Vaccine Against COVID-19

"A phase 2/3 study to assess the efficacy and safety of a recombinant adenovirus-based vaccine against Coronavirus Disease (COVID-19)"

IMPORTANT: If you or your child develop a fever or cough, shortness of breath or become unwell then you must contact the study team on <<contact details>> for advice before attending any visit.

Participation could really make a difference during a public health emergency.

We would like to invite your child to take part in our COVID-19 vaccine study. Before you make a decision, it is important you take the time to understand why we are doing this research and what it would involve. Please read the following information carefully and consider discussing it with friends and relatives.

What is the purpose of this research study?

The purpose of this study is to test how well a new vaccine works against COVID-19.

A new virus causing respiratory disease emerged in Wuhan, China in December 2019 and has since rapidly spread to many other countries around the world, despite unprecedented containment efforts. The virus is part of the Coronavirus family which may cause respiratory infections ranging from the common cold to more severe diseases. This recently discovered coronavirus causes COVID-19.

Common symptoms of COVID-19 include fever, tiredness, and dry cough. Whilst about 80% of infected people have no or mild symptoms and will recover from the disease without needing special treatment, 1 in every 6 people who gets COVID-19 becomes seriously ill. COVID-19 infections in children are less severe. Older people and those with underlying medical problems are more likely to develop serious illness. Thousands of deaths have been reported so far.

The WHO declared the COVID-19 epidemic a Public Health Emergency of International Concern on 30th January 2020 and a pandemic on 11th March 2020. This means that the epidemic is expected to spread to all countries of the world and infect 50-80% of people. There are no currently licensed vaccines or specific treatments for COVID-19. Vaccines are the most cost effective way of controlling outbreaks and the international community have stepped-up their efforts towards developing one against COVID-19.

This study will enable us to assess how well people across a broad range of ages may be protected from COVID-19 with this new vaccine called ChAdOx1 nCoV-19. It will also give us valuable information on safety aspects of the vaccine and how well participants' immune systems respond to immunisation with the vaccine.

Summary of the study

In total this study will enrol up to 10, 560 adults and children across the UK.

- Child participants will be randomised to receive one or two doses of either the *ChAdOx1 nCoV-19* or a licensed vaccine (MenACWY) that will be used as a 'control' for comparison

- Between 6 and 12 blood tests will be taken over the course of a year to check if there are any problems and to look at immune responses to the vaccine
- For some participants there will be a diary to complete for up to 28 days following vaccination
- There is a weekly questionnaire which will monitor participants and members of their households exposure to COVID-19
- In order to monitor for exposure to COVID-19, in those who do not develop symptoms we will perform weekly nasal swabs or saliva collection
- The study will take a year to complete

What is the vaccine we are testing?

The vaccine we are testing in this research study is called *ChAdOx1 nCoV-19*.

ChAdOx1 nCoV-19 is made from a virus (ChAdOx1), which is a weakened version of a common cold virus (adenovirus) from chimpanzees that has been genetically changed so that it is impossible for it to grow in humans. To this virus we have added genes that make proteins from the COVID-19 virus (SARS-CoV-2) called Spike glycoprotein (S), which play an essential role in the infection pathway of the SARS-CoV-2 virus. By vaccinating with ChAdOx1 nCoV-19, we are hoping to make the body recognise and develop an immune response to the Spike protein that will help stop the SARS-CoV-2 virus from entering human cells and therefore prevent infection. Vaccines made from the ChAdOx1 virus have been given to more than 320 people to date, and have been shown to be safe and well tolerated, although they can cause temporary side effects which are explained below (see section *Are there any risks from taking part in the trial?*).

The vaccine ChAdOx1 nCoV-19 was first given to 500 healthy adults in Oxford in April 2020 as part of a separate safety trial (COV001). Including in this current trial (COV002), the vaccine has now been given to approximately 2000 people in total with no unexpected safety concerns to date. The most up to date recruitment figures will be provided at the first visit.

We are not sure what dose of vaccine is most likely to be protective against COVID-19 disease. Vaccine doses are measured using standard scientific test methods. The vaccine received by the first approx. 1500 participants in the current COV002 trial was based on a dose measured using one type of scientific test. Participants in Group 6 will have a dose measured using a different type of scientific test which will give a higher dose of vaccine similar to the dose used in our earlier COV001 trial.

We are interested in evaluating both doses in the trial so that we can provide the data needed to inform policymakers on how to use the vaccine, if the vaccine is shown to work. This may help us understand which dose is the most effective.

We don't know which dose, if any, will provide protection. Although Group 4 received a lower dose, this does not mean that it will be better or worse than the higher dose, and we will study the immune response carefully to identify any differences. We are also considering whether 2 doses of the vaccine might be needed and will further investigate this when we obtain the first results of the ongoing trials.

We will give the injection with ChAdOx1 nCoV-19 or MenACWY into the muscle around the shoulder region; this is the most commonly used route for vaccination.

What is the control (comparison) vaccine, MenACWY?

In this study we will be using a licensed vaccine against group A, C, W and Y meningococcus (MenACWY) as an 'active control' vaccine, to help us understand participants' response to ChAdOx1 nCoV-19. MenACWY has been given routinely to teenagers in the UK since 2015, and protects against one of the most common causes of meningitis and sepsis. This vaccine is also given as a travel vaccine for high risk countries. We will be using one of the two versions of MenACWY, either Nimenrix or Menveo, both of which are licensed for use in 5 to 12 year olds. Children who have had these vaccines previously can still take part in this study.

Given we don't expect MenACWY to offer any protection against COVID-19, by comparing COVID-19 disease rates, immune responses and post-vaccination symptoms between participants receiving ChAdOx1 nCoV-19 and MenACWY we will get a better understanding of how well ChAdOx1 nCoV-19 is working.

Does my child have to take part?

No. It is up to you and your child to decide whether or not to take part. Your decision will not result in any penalty, or changes to your standard medical care. If you do decide that your child will take part, you will be given this information sheet to keep (or be sent it electronically) and will be asked to sign a consent form on behalf of your child. We would also provide some written information for you to read through with your child. You are free to withdraw at any time and without giving a reason, but we may request a follow up appointment for safety reasons.

Can my child take part?

In order to be involved in the study your child must:

- Be aged between 5 and 12 years (inclusive).
- Be able and willing (in the Investigator's opinion) to comply with all study requirements, including the follow up visits.
- for females of childbearing potential only, willingness to practice continuous effective contraception during the study and a negative pregnancy test on the day(s) of screening and vaccination

You must:

- Allow the Investigators to discuss your child's medical history with their GP and access all medical records.
- Provide informed consent on behalf of your child

Study participants cannot participate in this study if any of the following apply:

- are taking part in a COVID-19 drug trial
- are taking part in a serological study where you are informed if there is evidence of SARS-CoV-2 in your blood
- have any vaccine in the 30 days before or after this study vaccine
- have previously had other similar vaccines that might impact on understanding the study results such as adenovirus vectored vaccines or coronavirus vaccines
- have received immunoglobulins or blood products in the 3 months before having the study vaccine
- have immunosuppression or immunodeficiency
- have a history of angioedema
- have a history of anaphylaxis
- are have a current diagnosis or are having treatment for cancer
- have a history of serious psychiatric condition likely to affect participation in the study
- have a bleeding disorder
- continuously take anticoagulants, such as coumarins and related anticoagulants (i.e. warfarin) or novel oral anticoagulants (i.e. apixaban, rivaroxaban, dabigatran and edoxaban)

- have suspected or known current alcohol or drug dependency
- are pregnant, breast feeding or intend to become pregnant during the study
- have severe and/or uncontrolled cardiovascular disease, respiratory disease, gastrointestinal disease, liver disease, renal disease, endocrine disorder and neurological illness
- have a history of laboratory confirmed COVID-19 or a blood test shows that they have had contact with the COVID-19 virus

Mild conditions that are well-controlled would not automatically exclude your child from participating. If you are unclear whether your child is eligible to be involved in the study you can contact the study team who will be able to advise you.

What will happen if my child decides takes part?

The study visit plan for children is shown below.

	Screening	**Day 0**	**Day 3**	**Day 7**	**Day 28**	**Day 182**	**Day 365**	**COVID-19 Testing**	**COVD-19 Testing + 7 days**
								If necessary	
Vaccination		X							
Blood Tests	X	X	X*	X*	X	X	X	X	x
Diary		X	X	X	X				
Swab					Weekly from day 7			X	X

* To limit the amount of blood tests for each child there would be a blood test at either day 3 or 7, therefore only 5 blood tests (6 if followed for 1 year)

If your child decides to take part in this trial there is a short online questionnaire to complete to check that they are able to take part.

There will be a screening visit before the vaccination day. [If sites are not performing part screening visit by phone, delete] So that we can limit the amount of time you and your child spend face to face with a member of research staff we will conduct some of the visit with you over the phone. At the end of the online questionnaire you will be asked if you agree that a researcher can contact you by phone to ask questions about your child's current health and discuss details of your child's medical history in order to assess that they are eligible and if enrolled used as baseline health information. If your child is eligible you and your child will be invited to attend the second part of the visit.

Screening Visit – *1.5 hours (Listen to a consent presentation, ask any questions, sign a consent form, physical examination, medical history, temperature check, blood test and urine sample pregnancy test for some females)*

We will ask you to watch a video presentation of the information about the study to ensure you understand what to expect by taking part, the risks involved and what side-effects you might expect your child to experience. Then you will have opportunity to ask any questions of a member of the

research team before you as the parent/legal guardian sign a consent form on behalf of your child, if you and your child decide to take part. For children aged 11-12 years, there will be an assent form on which the child can 'sign' to indicate their agreement to take part. We do not require this of younger children as the concept of signing agreement may not be understood by them.

You can of course expect to receive full and comprehensive answers to any questions you may have.

You will be asked to agree to allow the research team to contact your child's own Doctor (GP) or check their medical records if more information about their health is needed. Having signed the appropriate forms, the research staff will go through a few questions for administrative purposes and detailed questions related to your child's health and medical history. This will be followed by a physical examination and a temperature check.

Females only: Girls will be asked if they have started their period. If they have, a urine sample will be tested for pregnancy at the screening visit and at the vaccination visit. If girls are sexually active they will be asked to make sure they use contraception for the whole study.

A blood sample will be taken to check if your child has had contact with the COVID-19 virus. If results indicate they have, your child will not be able to continue with the study. It is important to note that this is a research test that has not been validated for diagnostic purposes, so results cannot be used to provide certainty of prior infection nor of protection from future infection. We would use an anaesthetic cream to numb the skin for the blood test and a second person to distract your child if needed.

Vaccination Visit – *up to 1 hour (Temperature measured, blood test, nose swab or saliva sample, vaccination and up to 30 minutes observation after the vaccination)*

We will ask you a few questions to check there have been no new problems for your child since screening. We will check your child's temperature and we will take blood samples. Your child will be randomly allocated to receive one dose of ChAdOx1 nCoV-19 or MenACWY. This will be given as an injection at the top of the child's arm and we will cover the vaccine site with a dressing. We will need to keep an eye on your child to make sure they are OK for up to 30 minutes after the vaccine. Overall the visit will take up to one hour.

Electronic Symptom Diary "e-diary" – *Completed at home by participant*

We will give you a thermometer, tape measure and an E-diary account to record all your child's symptoms and temperature every day for 7 days after vaccination. After these 7 days we will ask you to record if your child is unwell or takes any medications over the next 3 weeks. The research staff will monitor the E-Diary and may phone you to ask for more information. You will also be asked to record in the diary any serious medical illnesses or hospital visits your child may have over the course of the study.

Weekly survey

We will send you a survey each week by email or text to enquire about COVID-19 symptoms of you and your household contacts for the duration of the study. If you work in a clinical area you will not be asked to complete this survey.

Follow up visits – *30 minutes (blood tests and check for side effects or new health problems)*

Following vaccination, there are a series of short follow up visits (lasting approx. 30 minutes)to ensure everything is fine and to check your child's symptoms. Blood tests will be performed as outlined in the table above.

Note: due to the high number of planned volunteers in this study, visits may take longer than the estimates given here

Weekly COVID-19 swabbing – *2 minutes plus time for posting*

In order to monitor for exposure to COVID-19 in those who do not develop symptoms we will ask you to collect weekly throat/nasal swabs or saliva samples from your child. These samples will be processed as part of the ongoing community testing programme conducted by the Department of Health and Social Care (DHSC). You will be given instructions about how to collect these samples yourself and how to send them to the laboratory for testing. For further information on how the DHSC will handle data from your weekly swabs, please see https://www.gov.uk/government/publications/coronavirus-covid-19-testing-privacy-information/testing-for-coronavirus-privacy-information-quick-read

If the results of your child's swab indicate that he or she has been exposed to COVID-19 or if your child develops symptoms of COVID-19 disease, we may ask you to collect a stool sample. You would receive instructions for how to collect the sample, how to use the packaging provided and how to arrange a courier to collect the sample.

We may ask to photograph the vaccination site. Your child will not be identifiable in these photographs, as only the vaccination site and the unique trial number will be visible. These photographs may be shown to other professional staff, used for educational purposes, or included in a scientific publication.

What should my child avoid during the trial?

Your child should not take part in other studies that involve the administration of drugs or vaccines, including trials testing other interventions for COVID-19. If during the trial your child is required to receive any vaccinations while enrolled in this study you should inform the research team beforehand and we will discuss with you the most appropriate time to receive them.

Are there any risks from taking part in the trial?

The risks and side effects of the proposed vaccinations and trial procedures are detailed here:

1. *Blood samples*

Drawing blood may cause slight pain, although we will use anaesthetic cream to numb the skin and a second person to distract your child. Occasionally there can be bruising at the site where the needle enters. Older children in particularly may feel light-headed or even faint. Taking blood from children can sometimes be difficult and we may ask you for a second attempt if needed. Depending on your child's age each blood sample would be a maximum volume of 16 to 20 ml (approximately 3 to 4 teaspoons).

The following blood tests will be performed:

- Tests of the immune responses to vaccines are done at most of the visits
- Tests of red and white blood cells, liver and kidney function are done at the first visit and most of the other visits in order to check the vaccines are safe.

If abnormal results or undiagnosed conditions are found during the course of the study these will be discussed with you and, if you agree, your GP (or a hospital specialist, if more appropriate) will be informed. Any newly diagnosed conditions will be looked after within the NHS. We will not be informing you of the results of your child's levels of immunity against the COVID-19 virus.

2. *Vaccination Side Effects: ChAdOx1 nCoV-19 and MenACWY*

It is likely that your child will experience some symptoms at the vaccination site as well as general symptoms due to vaccination. It is important to remember ChAdOx1 nCoV-19 is in the early stage of development and the amount of safety data available are limited. For this reason, there is a chance your child could experience a side effect that is more severe than what is described below, or that has not been seen before. This study is the first time ChAdOx1 nCoV-19 has been given to children.

Other ChAdOx1 viral vector vaccines have previously been administered in many other clinical trials. We can predict from past experience what the symptoms should be like with this new vaccine. We expect that symptoms will be mild in strength most of the time, although symptoms may also be moderate or severe. All symptoms should resolve completely within a few days. The chimpanzee adenovirus has been weakened so that it cannot grow in human cells. The SARS-CoV-2 protein it carries cannot cause COVID-19 disease.

The MenACWY vaccines are licensed vaccines, meaning they have been approved for use in the general population. They have been given to many hundreds of thousands of people, with no safety concerns.

a) Local Reactions at vaccination site

Following vaccination with either the *ChAdOx1 nCoV-19* or MenACWY vaccine your child may experience some discomfort at the injection site as the vaccination is given. This usually gets better within 5 minutes. Later, your child might experience pain at the injection site but this should resolve within a few days. In addition to pain, there may be some redness, swelling, itchiness or warmth at the injection site.

b) General reactions

During the first 24-48 hours after vaccination your child may experience flu-like symptoms such as muscle aches, joint aches, feverishness, chills, headache, nausea, tiredness and/or feeling generally unwell. These symptoms should usually resolve within a few days and can be experienced whichever vaccine your child is given.

c) Serious Reactions

With any vaccination there is a risk of rare serious adverse events, such as an allergic reaction. These may be related to the immune system or to the nervous system. Severe allergic reactions to vaccines (anaphylaxis) are rare, but can be fatal. In case of this unlikely event, medication for treating allergic reactions will be available and the research team are appropriately trained in the management of anaphylaxis. Reactions in the nervous system are also extremely rare, but can cause an illness called Guillain-Barré syndrome. This is a condition in which people can develop severe weakness and can be fatal. These adverse events have not previously been seen following administration of similar vaccines using ChAdOx1 as a viral vector.

With any new medicine or vaccine there is always a possibility of an unexpected side effect. You will be provided with a 24h study mobile number. If your child experiences unexpected events or you become in any way concerned about your child you can use this to contact one of the study doctors at any time. We will ask you to record these symptoms in the E-Diary too.

<u>Theoretical Concerns – could immunisation with ChAdOx1 nCoV-19 make COVID-19 disease worse?</u>

In the past, experimental vaccines were developed by different research groups against the SARS virus, which is in the same family as the COVID-19 virus and also infects the lungs. In some cases, animals that received certain types of experimental SARS vaccines appeared to develop *more severe* lung inflammation when they were later infected with SARS compared with unvaccinated animals. There has also been one report of this increased disease associated inflammation being seen in a mouse study for a vaccine against MERS-CoV (another related virus) but this has not been observed in any other reported animal studies. These problems were not seen in animal studies with ChAdOx1-MersCoV vaccine, which is very similar to the vaccine being used in this study, when the animals were exposed to the wild virus Studies of the ChAdOx1 nCoV-19 vaccine in animals are currently ongoing but: *we do not yet know whether this could also be a side effect of exposure to the pandemic COVID-19 virus in this COVID-19 vaccine study, whether this effect could occur in humans or whether this might lead to more severe COVID-19 disease in some cases.*

There have been recent reports of increased Kawasaki- like disease in children during the COVID-19 pandemic. Kawasaki disease is an illness that causes inflammation in the blood vessels in the body. A

fever that lasts for 5 days or more is the first sign. Since the cause of the COVID19-associated Kawasaki-like disease is unknown, it is not known if the immune response to the vaccine could also be a trigger or if this event will be more likely to occur in those who have been exposed to the virus after receiving the vaccine.

What are the advantages of taking part?

Your child will not necessarily gain any direct benefit from the trial, but the information gained from the study might help to develop an effective vaccine against COVID-19. If in the future your child is exposed to COVID-19, ***you should not assume that the vaccine you received in this study will give you any protection against COVID-19***. Participants who receive MenACWY will reduce their risk of meningitis and sepsis caused by group A, C, W or Y meningococcus.

What should you do if you believe your child may have developed COVID-19 during the study?

If you believe that your child may have COVID-19 while enrolled in the study then you must immediately inform the study team on <<contact details>>. Do not attend the clinical trial site unless you have been informed to by the study team. If you are at all unsure please contact the study team.

When calling to inform the study team that your child may have COVID-19 we will arrange for a COVID-19 testing visit. At this visit we will use a nose and/or throat swab to collect a sample and check if your child has the virus or not. We will also be taking a blood sample at this stage for safety and immunology monitoring. We will see your child again 7 days later to collect another swab and blood sample.

If your child is unwell and you are unable to contact the study team directly then contact the NHS 111 service or phone 999 if they are severely unwell.

If your child has a positive swab performed outside the study or is diagnosed as having COVID-19 disease while in the study then you must contact the study team and should not attend the clinical trial site until the trial team have informed you it is safe to do so. We would also contact you regularly to check your child's health.

If your child is admitted to hospital during the study then you should inform the medical or nursing staff that you are taking part in this trial. We will provide a contact card for you to give to these staff which will have a link to a website for them to fill in details about your admission.

It is important that you understand that if your child becomes seriously unwell and needs to be admitted to hospital, the standard referral routes within the NHS will be used. Participants will be treated the same way as the general population in this context of the COVID-19 pandemic. We are unable to offer extra medical support outside what is available within the NHS for the general public.

Will we be compensated for our travel?

Your child will receive a voucher as compensation for the time and travel at the end of the study/You will receive a refund for any costs required for parking at clinic visits.

What if new information becomes available?

Sometimes during the course of a trial, new information relevant to the trial becomes available. If this happens, we will tell you about it and discuss whether you want to, or should, continue in the study. If you decide your child will continue to take part, you will be asked to sign an updated consent form. On receiving new information, we may consider it to be in your child's best interests to withdraw them from the study. Your child's participation in this study may also be stopped at any time by the study doctor or the Sponsor for other reasons.

What will happen if I or my child doesn't want to carry on with the trial?

If, at any time after agreeing to participate, you or your child change your minds about being involved with this study you are free to withdraw without giving a reason. If your child withdraws we would not usually perform any more research procedures, although occasionally we might need to offer a follow

up visit for safety purposes, for example to check the injection site or a blood result. Your decision will not result in any penalty. Unless you state otherwise, any blood taken whilst your child has been in the study will continue to be stored and used for research as detailed above. You are free to request that the blood samples are destroyed at any time during or after the study. If you choose to withdraw from the trial, your standard medical care will not be affected.

What if something goes wrong?

The investigators recognise the important contribution that volunteers make to medical research, and make every effort to ensure your child's safety and well-being. The University of Oxford, as the research Sponsor, has arrangements in place in the unlikely event that your child suffer any harm as a direct consequence of participation in this trial.

In the event of harm being suffered, while the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further action and refer you to a doctor within the NHS for treatment, if necessary. NHS indemnity operates in respect of the clinical treatment which may be provided if you needed to be admitted to hospital.

Complaints statement

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the research investigators who will do their best to address your concerns by sending us an email to INSERT SITE EMAIL. Alternatively you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or the head of CTRG, email ctrg@admin.ox.ac.uk

Would my child taking part in this trial be kept confidential?

All information that is collected about your child during the course of the research will be coded with a study number and kept confidential. The information is available to the trial team, authorised collaborators, ethical review committees, INSERT LOCALTrust, government regulatory agencies and the Sponsor (University of Oxford), who can ask to access the trial data. Responsible independent monitors may be given access to data for monitoring and/or audit of the trial to ensure we are complying with regulations. They are bound by the same confidentiality rules. Any samples collected for the purposes of COVID-19 diagnosis and weekly swabbing might be sent to reference labs in the UK alongside your child's personal data. For the purposes of centralising the analysis of COVID-19 diagnosis and weekly surveillance results, the DHSC and NHS digital will send the results to the Sponsor (University of Oxford) and this may include personal data including medical records. If your child is diagnosed with COVID-19 during the course of the study then we must pass their details on to the local health protection team as COVID-19 is a "notifiable disease" and this is legal requirement in the UK.

If you consent to collect a stool sample when required; the stool sample (in an anonymised form) will be collected from you by a courier and processed in a laboratory by International Health Management Associates (IHMA), an accredited central laboratory. The sample will then be shipped for analysis by Astra Zeneca in a laboratory in the US. You would need to provide your childs name and address to the courier company.

Every effort will be taken to maintain confidentiality. Information about your child may be stored electronically on a secure server, and paper notes will be kept in a key-locked filing cabinet at the INSERT SITE NAME or at the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM), University of Oxford. Trial results will be published in a scientific journal but nothing that could identify your child will be included in any report or publication.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your child's information and using it properly.

We will be using information from you and your child's medical records in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information about your child such as contact details for a minimum of 5 years and until the youngest participant turns 21 years. The need to store this information for longer in relation to licensing of the vaccine will be subject to ongoing review. De-identified research data will be stored indefinitely. If you have agreed that samples can be retained for future research then your child's personally identifiable information will be kept with restricted access solely for the purposes of sample management for a minimum of five years after the last sample has been either used or disposed of in order to meet regulatory requirements. Samples will be provided for future research only in a form that does not identify you. We store research data securely at the University of Oxford indefinitely following removal of identifiable information. If you agree to your child's details being held to be contacted regarding future research, we will retain a copy of the consent form until such time as your details are removed from our database but will keep the consent form and your details separate

The study team will use your name and contact details, to contact you about the research study, and make sure that relevant information about the study is recorded for your child's care, in relation to your child's health during the study and to oversee the quality of the study. At the completion of the study, unless you consent otherwise (e.g. if you request to be informed of other trials), your child's personal details will not be used to contact you other than exceptional circumstances concerning your safety. If you consent to take part in another study carried out by the INSERT SITE NAME, personal information and medical information including blood test results may be accessed to avoid unnecessary repetition.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at: https://compliance.web.ox.ac.uk/individual-rights

Involvement of the General Practitioner (GP)/Family doctor (GP)

In order to enrol into this study, you will be required to sign a form documenting that you consent for us to contact your child's GP. Your child's GP may be asked to share information about your child's medical history and give access to any other medical records as required. We will write to your child's GP to let them know about your child's enrolment and study completion status, so they can update your child's medical records accordingly.

What will happen to any samples I give?

If you consent, some of your child's leftover blood samples can be stored and used for future infectious disease or vaccine related research. This is optional, your child's participation in this study will not be affected by your decision whether to allow storage and future use of leftover samples. Upon request at any time, your child's remaining blood samples will be destroyed.

Your child's study visit blood tests will be analysed in the site (hospital) laboratories and Oxford University research laboratories. Other blood tests to look at the response of your child's body to the vaccine will be done with collaborating laboratories in the UK and in other countries. Any samples or data sent to them would not include information that identifies your child.

Your child's weekly swab tests for COVID-19 will be performed in partnership with the Department of Health and Social Care national community testing programme.

Will any genetic tests be done?

We may do genetic tests on your child's blood samples to look at the patterns of genes that regulate their own individual immune response (these are called Human Leukocyte Antigen genes). Doing this helps us to work out which aspects of the immune response to vaccines are due to genetic differences between individuals. We may also look at the expression of certain genes which relate specifically to

the immune response to COVID-19, but no genetic tests concerning diseases or conditions other than COVID-19 and other vaccine related responses.

What will happen to the results of the research study?

The results of this research study may be presented at scientific meetings or conferences and published in a scientific medical journal. This may not happen until 1 or 2 years after the study is completed. A copy of the results will be made available to you after the study. Your child will not be identified in any report or publication.

The de-identified data from this study will be shared with the collaborating partners who are organising and funding this research work. Data from this study may be used to file patents, licence vaccines in the future or make profits in other ways. You will not be paid for any part of this. Data from this study may be used as part of a student post-graduate degree, for example a MD or PhD.

Taking part in future vaccine-related research

With your consent, we would like to keep your child's contact details after their participation in this study is complete, so we may inform you of opportunities to participate in future vaccine related research. This is entirely optional and your child's participation in this study will not be affected by your decision to allow or not allow storage of your contact details beyond your participation in this trial.Your child's details will be stored electronically on a secure server and only authorised individuals at the INSERT SITE NAME will have access to it.

We will not, under any circumstances, share your child's contact details with any third party institutions without your permission. Being contacted does not oblige you to agree to take part in future research and you can ask us to have your child's contact details removed from our database at any time.

Who is sponsoring, organising and funding the research?

The study is organised and sponsored by the University of Oxford. The study is funded through financial support to the University of Oxford from the National Institute for Health Research (NIHR), which is a UK government funded research agency. Neither your child's GP nor the researchers are paid for recruiting you into this study.

Who has reviewed the study?

This study has been reviewed by the NHS Research Ethics Service (RES) – South Central – Berkshire and has been given a favourable ethical opinion. The Medicines and Healthcare products Regulatory Agency (MHRA), which regulates the use of all medicines in the UK, has reviewed the study design and has granted permission to use this unlicensed vaccine in this clinical study.

Further information and contact details

We hope this information sheet has answered all of your questions. If you would like further information about participating in research please visit the following website: http://www.nhs.uk/conditions/Clinical-trials/Pages/Introduction.aspx. For independent advice about participating in this trial you may wish to contact your GP. If you would like to speak to one of our team members to discuss any aspect of this trial or **if you are interested in taking part in the study, please contact us**:

<<Insert Site recruitment contact details (address, email, phone)>>